

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Art Unit: 1624
BOLLBUCK et al. Examiner: E. O. Sackey
APPLICATION NO: 10/532,331
FILED: April 22, 2005
FOR: 1-(4-BENZYL-PIPERAZIN-1-YL)-3-PHENYL-PROPENONE
DERIVATIVES

MS: General
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION REGARDING PATENT TERM ADJUSTMENT POST GRANT UNDER C.F.R.
§1.705(d)

Sir:

In accordance with 37 C.F.R. § 1.705(d), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of 963 days. This application is being filed within two months of the date the patent issued, as required by 37 C.F.R. § 1.705 (d).

As an initial matter, Applicants appreciate the information provided in the Office of Petitions letter dated December 1, 2009 regarding the preliminary petition for patent term adjustment filed August 24, 2009. A copy of the letter is enclosed herewith.

I. Fee

The Office acknowledged receipt of the petition fee of \$200.00 required by 37 C.F.R. §1.705(b)(1) in the letter dated December 1, 2009. The letter further indicated that no additional fees are required for consideration of the instant petition. Please charge any deficiencies or any additional fees due in response to this request to Deposit Account **50-4409**.

II. Statement of the Facts Involved

A. Correct Patent Term Adjustment

The Issue Notification, which was mailed on January 12, 2010, indicates a Patent Term Adjustment of 648 days.

Patentee has calculated an initial patent term adjustment of 963 days based on the following facts:

Case Law

In *Wyeth v. Kappos*, 2010 U.S. App. Lexis 300, the Federal Circuit affirmed the interpretation of 35 U.S.C. § 154(b)(2) by the District Court of the District of Columbia in *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 2008. The Federal Circuit affirmed the determination that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2)(B) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(2)(A) period and a 35 U.S.C. § 154(b)(2)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(2)(A) period that falls outside of the 35 U.S.C. § 154(b)(2)(B) period in addition to the 35 U.S.C. § 154(b)(2)(B) period itself.

Relevant Dates

The above identified application has a 35 U.S.C. §371 filing date of April 25, 2005.

The first Office Action was mailed on March 24, 2008, resulting in a PTO delay of 638 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response by Applicant was filed July 3, 2008, which was nine (9) days after the expiry of the 3 months provided by 35 U.S.C. §154(b) resulting in an Applicant delay of 9 days.

A Final Office Action was mailed October 14, 2008, within the 4 months provided by 35 U.S.C. §154(b).

A Response by Applicant and Notice of Appeal were filed January 8, 2009, within the 3 months provided by 35 U.S.C. §154(b).

An Advisory Action was mailed February 9, 2009, within the 4 months provided by 35 U.S.C. §154(b).

A Request for Continued Examination by Applicant was filed March 6, 2009, within the 3 months provided by 35 U.S.C. §154(b).

A Preliminary Amendment by Applicant was filed May 18, 2009 responsive to a request by the Examiner during a telephonic interview occurring on the same date.

A Notice of Allowance was mailed May 29, 2009, within the 4 months provided by 35 U.S.C. §154(b).

The issue fee has been paid on August 24, 2009 within the 3 months provided by 35 U.S.C. §154(b).

The patent was issued January 12, 2010, resulting in a PTO delay of 19 days beyond the 4 months provided by 35 U.S.C. §154(b).

Accordingly, the initial PTO adjustment based on delay under 35 U.S.C. § 154(b)(2)(A) is 657 days.

The initial 35 U.S.C. § 154(b)(2)(B) period for the instant application began on April 25, 2008 (three years after the filing date of April 25, 2005) and ended on March 6, 2009, e.g., the filing date of the Request for Continued Examination. The initial 35 U.S.C. § 154(b)(2)(B) period running from April 25, 2008 until filing of the Request for Continued Examination (March 6, 2009) is 315 days.

There was 0 days of PTO delay under 35 U.S.C. § 154(b)(2)(A) that occurred within the initial 35 U.S.C. § 154(b)(2)(B) period that should be excluded from the patent term adjustment calculation under the holding of *Wyeth v. Dudas*.

There were 9 days of Applicant delay under 35 U.S.C. §154(b)(2)(C).

Accordingly, the sum of the 35 U.S.C. § 154(b)(2)(B) delay (315 days) and 35 U.S.C. § 154(b)(2)(A) delay (657 days) less the overlap days (0 days) and less Applicant delay days (9 days) results in a PTA of 963 days.

The initial PTA printed on the Issue Notification is only 648 days, which the USPTO is presumed to have calculated using the method considered proper before the holding of *Wyeth v. Dudas*. Applicants therefore respectfully request reconsideration of the initial PTA calculation.

B. Terminal Disclaimer


The above-identified patent is not subject to a Terminal Disclaimer.

C. Reasonable Efforts

Any applicant delays under 37 C.F.R. § 1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

Respectfully submitted,

Novartis Institutes for BioMedical Research, Inc.
220 Massachusetts Avenue
Cambridge, MA 02139
(617) 871-5027



Sophie Binet Cross
Agent for Applicant
Reg. No. 59,494

Date: February 1, 2010